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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,154	07/03/2002	Toshio Ota	084335-0158	1489

22428 7590 12/02/2004

FOLEY AND LARDNER
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EXAMINER

BLANCHARD, DAVID J

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/048,154

Applicant(s)

OTA ET AL.

Examiner

David J Blanchard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claim 11 is drafted as a non-statutory "use" claim (see MPEP 2173.05(q)).

Accordingly, claim 11 is withdrawn from consideration.

2. In addition to electing one of inventions I-VIII below, Applicant is required to further elect one of the claimed nucleic acid sequence (for Groups I, VI and VII) or one of the claimed polypeptides (for Groups II-V and VIII). See item # 4 below.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a polynucleotide having the nucleotide sequence of SEQ ID NO:1. In view of this Jacobs et al (WO 98/37094, 8/27/1998) reads on the claim. Jacobs et al teach a nucleic acid (SEQ ID NO:1; 91% sequence identity with instantly claimed SEQ ID NO:1) that would hybridize to the polynucleotide of SEQ ID NO:1 under stringent conditions. Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

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Group I, claims 1, 2, 4-5 and 7 in part, drawn to a nucleic acid, a vector and host cells.

Group II, claim 3 in part, drawn to a protein encoded by a polynucleotide of claim 1.

Group III, claim 6 in part, drawn to a method of making a protein of claim 3.

Group IV, claim 8 in part, drawn to an antibody that binds a protein of claim 3.

Group V, claim 9 in part, drawn to an immunological assay for detecting a protein of claim 3 with an antibody.

Group VI, claim 10 in part, drawn to a method of screening for a compound that controls the expression of a polynucleotide of claim 1.

Group VII, claim 12 in part, drawn to a method for detecting stomach cancer comprising measuring a polynucleotide of claim 1.

Group VIII, claim 13 in part, drawn to a method for detecting stomach cancer comprising measuring a protein of claim 3.

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4. For each of Invention sets I-VIII above, Applicant is required to elect one of Inventions I-VIII and a single claimed sequence for examination. The inventions of Groups I-VIII (claims 1-10 and 12-13) can be classified into 75 different groups of inventions relating to a DNA or a polypeptide sequence that do not constitute a group of linked inventions as to form a single general inventive concept.

5. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Jacobs et al the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

Inventions of Groups I, II and IV represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The polynucleotide, vector and host cells of Group I, the polypeptide of Group II and the antibody of Group IV are all structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, the polypeptide is made by translation of mRNA and the antibody is raised by immunization. Furthermore, the polynucleotide can be used for hybridization screening, the polypeptide can be used to raise antibodies and the antibody can be used to purify the antigen, for example. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific

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literature and would require the consideration of different patentability issues. Thus the inventions I, II and IV are patentably distinct.

The methods of Inventions III and V-VIII differ in the method objectives, method steps and parameters and in the reagents used. Invention III recites a method of making a polypeptide of claim 3; Invention V recites an immunological assay for detecting a protein of claim 3 with an antibody; Invention VI recites a method of screening for a compound that controls the expression of a polynucleotide of claim ; Invention VII recites a method for detecting stomach cancer comprising measuring a polynucleotide of claim 1; Invention VIII recites a method for detecting stomach cancer comprising measuring a protein of claim 3. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions III and V-VIII are separate and distinct in having different method objectives, method steps and parameters and in the reagents used and are patentably distinct.

Inventions III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of Group II can be made by in vitro chemical synthesis in addition to the materially different in vivo process of Group III.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group IV can be used in a materially different method such as to purify the antigen in addition to the materially different method of Group V.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group I can be used in a materially different method such as the materially different method of Group VII.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

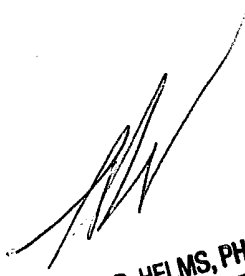
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by

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telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The official fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827



LARRY R. HELMS, PH.D
PRIMARY EXAMINER